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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/812,897 | 03/31/2004 | Ok-Kyung Cho | 1021.43730X00 | 5002 |

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| EXAMINER | |
|---|---|
| WINAKUR, ERIC FRANK | |
| ART UNIT | PAPER NUMBER |
| 3768 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/11/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/812,897 | CHO ET AL. | |
| | Examiner | Art Unit | |
| | Eric F. Winakur | 3768 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 31 March 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner:

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date See Continuation Sheet.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/31/04; 5/3/04; 7/6/04; 12/16/04; 3/16/05; 4/13/05; 6/9/05; 8/11/05.

## DETAILED ACTION

### *Claim Objections*

1. Claims 1 - 4 are objected to because of the following informalities: With regard to claim 1, it appears that the phrase "an indirect temperature detector for detecting the concentration" should refer to detecting "the temperature". Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 refers to "a storage portion where information about blood hemoglobin concentration and hemoglobin oxygen saturation is stored". However, contrary to the disclosure that details that this information is required when calculating the blood sugar level, this information is not used by the "calculating portion" as set forth in the claim. Thus, the relationship between the information and the calculation portion does not appear to be clearly set forth.

### *Double Patenting*

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 - 8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 15 of U.S. Patent No. 6,954,661. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the patent with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended purpose. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

6. Claims 1 - 8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 7,120,478. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the patent with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended purpose. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

7. Claims 1 - 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, and 12 of copending Application No. 10/879,780. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a

threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the copending application with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended purpose. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1 - 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, and 11 of copending Application No. 11/059,607. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the copending application with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level

of the art to modify an apparatus to include well known elements for their intended purpose. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claim 9 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13 of copending Application No. 10/765,986. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the copending application with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1 - 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 10/620,689. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the copending application with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended purpose. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1 - 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 11/169,777. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application

disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims and particularly computing a blood sugar level, as the copending application computes "metabolic characteristics". However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the copending application with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended purpose. In addition, it would have been within the skill level of the art to identify "metabolic characteristics" of medical interest for monitoring by the apparatus of the copending application, including blood sugar level. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1 - 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, and 13 of copending Application No. 11/008,360. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending

application disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the copending application with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended purpose. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1 - 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, and 9 of copending Application No. 10/879,231. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to

one of ordinary skill in the art at the time of the invention to implement the apparatus of the copending application with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended purpose. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1 - 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, and 11 of copending Application No. 10/813,241. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the copending application with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended

purpose. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1 - 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, and 11 of copending Application No. 10/811,894. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the copending application with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended purpose. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1 - 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, and 14 of copending Application No. 10/813,029. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application disclose all of the elements of the claim of the instant application except for a warning control portion, as set forth in the claims. However, it was well known in the art at the time of the invention to compare a calculated blood sugar level with a threshold and trigger an alert if high levels are detected. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the apparatus of the copending application with a warning control portion to allow a user to be alerted to dangerous medical conditions since it has generally been held to be within the skill level of the art to modify an apparatus to include well known elements for their intended purpose. Further, it was within the skill level of the art at the time to implement multiple threshold comparisons for indicating different potentially dangerous conditions and to utilize either predetermined or user variable set points for the thresholds, as these are well known details for implementing threshold-based alerts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant cites several references related to measurement of analyte concentrations. Of particular relevance, Oosta et al. (USPN 5,725,480) teach use of temperature measurements, among other factors, to calibrate optical glucose measurements based upon a subject's skin type. Cho (WO 01/28414) suggests determining glucose concentrations based upon analysis of temperature and spectral measurements. However, the prior art does not teach or suggest a blood sugar level measuring apparatus that includes a measuring arrangement that obtains a plurality of temperatures from a subject's body surface, a computing unit for converting measurement values provided from the temperature measurements and oxygen volume measurements into parameters which are used for computing a blood sugar level based on a stored relationship, and further including a warning control portion, in combination with the other claimed elements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric F Winakur
Primary Examiner
Art Unit 3768